REMARKS/ARGUMENT

Description of Amendments

Claims 1, 2, 4, 6, and 9-18 are now pending and under examination, and claims 3, 5, 7, 8, and 19-25 are withdrawn. Applicant has amended claims 1, 17, and 18. No new matter has been added.

The amendments to claims 1, 17, and 18 are supported by the application as originally filed (see, for example, paragraph [0065]).

Information Disclosure Statement of Sep. 1, 2004

The Examiner refused to consider the Information Disclosure Statement (IDS) of Sep. 1, 2004 on the ground that the IDS does not include a 1449 form. Applicant's counsel has inspected his file but could not find an IDS filed on Sep. 1, 2004. Applicant respectfully requests a clarification.

Rejection under 35 U.S.C. §112, Second Paragraph

Claims 12 and 17 were rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

Regarding claim 12, the Examiner contended that the limitation that "sleeve portion includes a pattern of struts" is ambiguous on the ground that paragraph [0015] of the specification states that the struts are elements of the stent not the sleeve. Applicant respectfully disagrees.

It is true that paragraph [0015] of the specification states that a stent has a pattern of struts. However, contrary to the Examiner's contention, the paragraph does not state that struts are not elements of the sleeve. In fact, the specification specifically states that "[t]he polymeric sleeve is fabricated from a predesigned pattern...[and] the predesigned pattern may...include a plurality of struts... (paragraph [0064])."

It should be pointed out that the term "strut" merely describes a structural element, and the structural element may be a part of the stent or of the sleeve. The fact that struts are

described as elements of the stent does not mean that struts cannot also be elements of the sleeve.

In view of the above remarks, Applicant respectfully submits that the rejection of claim 12 is improper, and respectfully requests reconsideration and withdrawal of the rejection.

Regarding claim 17, the Examiner contended that the claim scope is unclear because it is not clear whether the stent is being positively claimed.

Applicant respectfully submits that claim 17 does not positively recite the stent. Claim 17 is directed to a sleeve. The stent is not part of the claimed sleeve and merely defines the environment in which the claimed sleeve is placed. The same can be said about claims 1 and 18.

Rejection under 35 U.S.C. §102

Claims 1, 2, and 10-18 were rejected under 35 U.S.C. §102(b) as being anticipated by Tartaglia (U.S. Patent 5,700,286). For the following reasons, Applicant respectfully requests reconsideration and withdrawal of the rejection.

One disadvantage of a prior art drug eluting stent is that when the stent is expanded, the drug-coated stent surfaces are stretched, causing uneven distribution of coated drug on stent surfaces. One object for the present invention is to overcome this disadvantage of the prior art.

In each of independent claims 1, 17, and 18, the sleeve includes independent drug-loaded elements, wherein the sleeve is not stretched when the stent structure expands from the unexpanded condition to the expanded condition. Consequently, the expansion of the stent structure does not cause an uneven distribution of coated drug.

Tartaglia discloses an expandable stent structural member (22) and **a** planar sheet or film (24) of polymeric material that is wrapped around the stent (column 4, lines 19-49). The Examiner contended that the planar sheet or film (24) is the sleeve of the claimed invention. Applicant respectfully disagrees.

The sleeve of the claimed invention includes **independent** drug-loaded element**s**. Tartaglia discloses only a single planar sheet or film (24). The single planar sheet or film

(24) cannot be **independent** drug-loaded elements. Additionally, the sleeve of the claimed invention is not stretched when the stent structure expands from the unexpanded condition to the expanded condition. In Tartaglia, the planar sheet or film (24), which is wrapped around the stent structural member (22), will be stretched when the stent structural member (22) expands.

In view of the above remarks, Tartaglia does not teach the limitation of independent drug-loaded elements and the limitation that the sleeve is not stretched when the stent structure expands from the unexpanded condition to the expanded condition. Accordingly, Tartaglia does not anticipate independent claims 1, 17, and 18. Dependent claims 2 and 10-16 are also not anticipated because they depend from claim 1.

Rejection under 35 U.S.C. §103(a)

Claims 1, 2, 4, and 9-18 were rejected under 35 U.S.C. §103(a) as being unpatentable over Williams (U.S. Patent 5,707,385) in view of Tartaglia. For the following reasons, Applicant respectfully requests reconsideration and withdrawal of the rejection.

Williams discloses an expandable stent (16) stent and **an** expandable membrane (5) that is mounted on the expandable stent (see Abstract). When the stent (16) is expanded, the expandable membrane (5) is stretched (see claim 1 and column 2, lines 30-41). The Examiner conceded that Williams does not discloses a sleeve that includes independent drug-loaded elements, but contended that Tartaglia teaches a sleeve including independent elements separated by slits (30).

Applicant respectfully disagrees with the Examiner's reading of Williams and Tartaglia. First, Tartaglia does not teach a sleeve including independent elements separated by slits (30). It is true that the single planar sheet or film (24) of Tartaglia includes slits (30). However, the slits (30) do not create independent elements. In fact, the portions of the sheet or film (24) separated by the slits (30) are integral parts of the sheet or film (24) and are directly and integrally attached to one another. The fact that a slit is cut in a sheet does not make the sheet two separate parts. Therefore, these portions are not independent elements.

Second, neither Williams nor Tartaglia teaches the limitation that the sleeve is not stretched when the stent structure expands from the unexpanded condition to the expanded

condition. As explicitly taught by Williams, its expandable membrane (5) is designed to stretch when the stent (16) expands from the unexpanded condition to the expanded condition (see claim 1 and column 2, lines 30-41). In Tartaglia, the planar sheet or film (24), which is wrapped around the stent structural member (22), will be stretched when the stent structural member (22) expands.

In view of the above remarks, the cited art does not teach each and every limitation of independent claims 1, 17, and 18. Accordingly, independent claims 1, 17, and 18 are patentable over the cited art. Dependent claims 2, 4, and 9-16 are also patentable because they depend from patentable claim 1.

Claims 1, 2, 4, 6, and 9-18 were rejected under 35 U.S.C. §103(a) as being unpatentable over Williams in view of Layne (U.S. Patent Publication 2001/0032009). For the following reasons, Applicant respectfully requests reconsideration and withdrawal of the rejection.

This rejection is similar to the previous §103(a) rejection except that Tartaglia is replaced by Layne. Layne teaches a sleeve of ePTFE (40) placed over a stent (20) (see paragraph [0022]). The sleeve (40) is slid over the stent (20) and then exposed to heat and pressure, thereby causing the sleeve (40) to fuse or laminate to the stent (20) wherever they touch each other (paragraph [0022]). Layne also teaches cutting slits (52) in the sleeve (40) so as to leave critical parts of the stent (20) unencapsulated to facilitate flexibility and expansion (paragraph [0024]).

However, Layne suffers from the same deficiencies as Tartaglia. Like Tartaglia, Layne does not teach a sleeve including independent elements. The sleeve (50) of Layne does include slits (52). However, the slits (52) do not create independent elements. In fact, the portions of the sleeve (50) separated by the slits (52) are integral parts of the sleeve (50) and are directly and integrally attached to on another.

Layne also does not teach the limitation that the sleeve is not stretched when the stent structure expands from the unexpanded condition to the expanded condition. The sleeve (40) of Layne is fused or laminated to the stent (20). Therefore, when the stent (20) expands, some portions of the sleeve (40) necessarily expand, causing an uneven distribution of coated drug.

In view of the above remarks, the cited art does not teach each and every limitation of independent claims 1, 17, and 18. Accordingly, independent claims 1, 17, and 18 are patentable over the cited art. Dependent claims 2, 4, 6, and 9-16 also are patentable because they depend from patentable claim 1.

In light of the foregoing remarks, this application is considered to be in condition for allowance, and early passage of this case to issue is respectfully requested. If necessary to effect a timely response, this paper should be considered as a petition for an Extension of Time sufficient to effect a timely response, and please charge any deficiency in fees or credit any overpayments to Deposit Account No. 07-1850.

Respectfully submitted,

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